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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,159

10/13/2006

Dawn Patricia Wooley

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EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

03/15/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/569,159	Applicant(s) WOOLEY ET AL.	
	Examiner MICHAEL BURKHART	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12 and 16-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/21/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/2006</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1633

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 12/23/2010 is acknowledged. The traversal is on the ground(s) that Mansky et al do not teach the special technical feature linking the inventions, as asserted by the Examiner. Specifically, applicants make numerous references to limitations found the method claims (Group II), but not in the vector claims (i.e. Group I). This is not found persuasive because the vector claims, i.e. claim 1, are not limited by the vector claims (i.e. claim 17). The fact remains that claim 1 is anticipated by several prior art references (see below), as such, the technical feature linking claims 1 and 17 (i.e. the vector of claim 1) is not a special technical feature. Thus, the Groups are not linked to form a single inventive concept. The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 12, and 16-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/23/2010.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1633

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-10, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcello et al (Res. Vir., 1998).

Marcello et al teach a replication defective HIV-1 vector comprising deletions in the gag, pol, and env genes. The vector also comprised the hygromycin resistance and herpes virus thymidine kinase genes separated by an IRES sequence, with the HIV LTR as a promoter. See the abstract, Fig. 1, page 421, first column, first full ¶ and page 423, ¶ linking the first and second columns. In the system of Marcello et al, the vector is transduction and infection competent for Jurkat cells, see the column linking pages 424-425. The vector comprised the hygromycin resistance gene (Fig. 1, abstract). This is considered to be the hygromycin B resistance gene, absent evidence to the contrary, as it was used as a positive selection marker against hygromycin (page 422, second column), and the art is devoid of any antibiotic considered "hygromycin" other than "hygromycin B." The vector comprised the thymidine kinase gene (TK), see Fig. 1 and the abstract in particular, which is considered a "mutational target gene" by the instant claims and specification. The herpes virus TK gene used by Marcello et al is considered to inherently be 996 bp long, as taught by the instant specification, absent any evidence to the contrary. The vector was used in both COS-1 and Jurkat cells (Figs 2 and 3 at least), both of which are considered "dividing cells" as they were grown in cell culture (page 422, first and second columns).

Art Unit: 1633

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galipeau et al (WO 00/65034, 11/2/2000) in view of Naldini et al (PNAS, 1996).

Galipeau et al teach a replication defective retroviral vectors comprising a CMV promoter driving expression of the HSV-TK and EGFP genes separated by an IRES followed by

Art Unit: 1633

a retroviral LTR. See the abstract, Fig. 1B ("pTKiGFP"), Fig. 9B, claims 2-5 and 10-12. EGFP is considered a positive marker gene in this instance, absent any limiting definition of such in the instant specification, due to the use of EGFP as an expression and infection marker by Galipeau et al (e.g. see pages 12, 28 and 31 of Galipeau et al). In the system of Galipeau et al, the vector is transduction and infection competent for 293 and mouse glioma and DA3 cells, see pages 12-15 and 28. The vector comprised the HSV thymidine kinase gene (TK), as set forth above, which is considered a "mutational target gene" by the instant claims and specification. The herpes virus TK gene used by Galipeau et al is considered to inherently be 996 bp long, as taught by the instant specification, absent any evidence to the contrary. The 293 and mouse tumor cells are considered "dividing cells" as they were grown in cell culture or in vivo.

Galipeau et al do not teach a lentivirus-based vector (lentiviruses are a subset of retroviruses), nor the specific disruption of the gag, pol, and env genes, although this is implied due to the use of replication defective vectors and 293 packaging cells that supply the disrupted genes.

Naldini et al teach a HIV-1 based vector that is replication-defective via major deletions in the gag, pol and env genes (page 11382, second column, page Fig. 1, pHR'). The transgene in this case was driven by the CMV promoter (Fig. 1, pHR').

The claimed vectors are essentially disclosed by Galipeau et al with the exception of the lentivirus-based limitation. The ordinary skilled artisan, seeking a viral gene therapy vector to deliver the TK gene of Galipeau et al, would have been motivated to use the HIV-1 vector of Naldini et al with the bicistronic transgene encoding TK and EGFP of Galipeau et al because Naldini et al teaches the HIV-1 system to have utility for infecting a diverse array of dividing

Art Unit: 1633

and non-dividing mammalian cells. It would have been obvious for the skilled artisan to do this because of the known benefit of generating retro- or lentiviral vectors for delivery of transgenes as taught by both Galipeau and Naldini et al. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhardt/
Primary Examiner, Art Unit 1633